

5. 510(k) SUMMARY:

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510(K) Summary of Safety and Effectiveness:

SUBMITTER: Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien)
60 Middletown Avenue
North Haven, CT 06473

CONTACT PERSON: Rebecca Ronner
Associate, Regulatory Affairs
Phone: (203) 492-5346
Fax: (203) 492-5029

DATE PREPARED: June 24, 2009

TRADE/PROPRIETARY NAME: Absorbatack™ Absorbable Fixation Device

COMMON/USUAL NAME: Absorbable Tack and Applicator

CLASSIFICATION NAME: Implantable Staple

PREDICATE DEVICE(S): K071920 - Absorbatack™ Absorbable Fixation Device
Note: There are no modifications to the previously cleared devices.)

DEVICE DESCRIPTION: Absorbatack™ Absorbable Fixation Devices are sterile single use devices for the fixation of prosthetic material such as hernia mesh to soft tissue. The Tack is constructed of an absorbable synthetic polyester copolymer derived from lactic and glycolic acid. The device is offered with of 5, 10 or 20 tacks.

INTENDED USE: Absorbatack™ Absorbable Fixation Devices are intended for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures such as hernia repair.

TECHNOLOGICAL CHARACTERISTICS: Absorbatack™ Absorbable Fixation Device is identical to the predicate device.

MATERIALS: CHARACTERISTICS: Absorbatack™ Absorbable Fixation Devices is comprised of materials which have been evaluated in accordance with ISO 10993-1: 2003, Biological Evaluation of medical devices – Part I Evaluation and Testing and is identical to the predicate device

PERFORMANCE DATA: CHARACTERISTICS: There has been no change to the Absorbatack™ Absorbable Fixation Device. The modified labeling for the subject device is based on performance testing obtained for the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2009

Covidien LP
% Ms. Rebecca Ronner
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K091900

Trade/Device Name: Absorbatack™ Absorbable Fixation Device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: June 24, 2009
Received: June 25, 2009

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT:

510(k) Number (if known): K091900

Device Names: Absorbatack™ Absorbable Fixation Device

Indications For Use The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MSK
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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